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**EURASIAN ECONOMIC COMMISSION
BOARD**

DECISION

June 30, 2017

No. 78

city of Moscow

**On the Requirements to the Electronic Form of Applications and Documents
of the Registration Dossier Submitted when Registering and Examining
Safety, Quality and Efficacy of Medical Products**

In accordance with paragraph 11 of the Protocol on Information and Communication Technologies and Information Interaction within the Eurasian Economic Union (Annex No. 3 to the Treaty on the Eurasian Economic Union dated May 29, 2014) and the Rules for Registration and Examination of Safety, Quality and Efficacy of Medical Products approved by Decision No. 46 of the Council of the Eurasian Economic Commission dated February 12, 2016 (hereinafter referred to as the “Rules for Registration”), the Board of the Eurasian Economic Commission **decided**:

1. To approve the attached Requirements to the electronic form of applications and documents of the registration dossier submitted when registering and examining safety, quality and efficacy of medical products (hereinafter referred to as the “Requirements”).

2. To establish that development of technical schemes of document structures in electronic form provided for by the Requirements and their placement in the register of electronic documents and details published on the official website of the Eurasian Economic Union (hereinafter referred to as the “Union”) are carried out by the Department of the Eurasian Economic Commission, the competence of which includes coordination of works on creation and development of the integrated information system of the Union.

3. To establish that when electronic forms of interaction are implemented in the Member States of the Union, documents in electronic form provided for by the Requirements are applied in accordance with the Rules for Registration in accordance with the technical schemes of the structures of such documents contained in the register of electronic documents and details structures.

4. This Decision shall enter into force after 30 calendar days have elapsed from the date of its official publication.

Chairman of the Board of the
Eurasian Economic
Commission

T. Sargsyan

Seal:

Eurasian Economic Commission. For documents

APPROVED
by Decision No. 78 of the Board of
the Eurasian Economic Commission
dated June 30, 2017

REQUIREMENTS
to the electronic form of applications and documents of the registration
dossier submitted when registering and examining
safety, quality and efficacy of medical products

I. General provisions

1. These Requirements are developed to create equal conditions for business entities of the Member States of the Eurasian Economic Union (hereinafter referred to as the “Member States”, the “Union”, respectively) on electronic submission of details to the authorized authorities of the Member States (expert organizations) when carrying out procedures for registration and examination of safety, quality and efficacy of medical products.

2. The terms used in these Requirements are applied in the meanings defined by the Protocol on Information and Communication Technologies and Information Interaction within the Eurasian Economic Union (Annex No. 3 to the Treaty on the Eurasian Economic Union dated May 29, 2014) and the Rules for Registration and Examination of Safety, Quality and Efficacy of Medical Products approved by Decision No. 46 of the Council of the Eurasian Economic Commission dated February 12, 2016 (hereinafter referred to as the “Rules for Registration”).

3. These Requirements determine the structure and rules for filling out of documents in the electronic form, submitted by the applicant to the authorized authorities of the Member States when performing procedures provided for in the Rules for Registration.

4. The structure of the document in electronic form “Details on application for registration of a medical product within the Eurasian Economic Union” (R.018) is intended for submission of the following types of applications in electronic form:

a) application for examination of a medical product within the Union - in accordance with Annex No. 2 to the Rules for Registration (hereinafter referred to as the “application for examination”);

b) application for registration of a medical product within the Union, submitted in accordance with Annex No. 3 to the Rules for Registration (hereinafter referred to as the “application for registration”);

c) application for introduction of changes to the registration dossier of a medical product within the Union, submitted in accordance with Annex No. 7 to the Rules for Registration (hereinafter referred to as the “application for change”);

d) application for cancellation (annulment) of a registration certificate for a medical product submitted in accordance with Annex No. 10 to the Rules for Registration (hereinafter referred to as the “application for cancellation”);

e) application for the issuance of a duplicate of the registration certificate for a medical product submitted in accordance with Annex No. 11 to the Rules for Registration (hereinafter referred to as the “application for the issuance of a duplicate”).

5. The structure of the document in electronic form “Details on documents of the medical product registration dossier or documents executed during examination of the medical product registration dossier” (R.020) is intended to present documents of the medical product registration dossier in electronic form in accordance with Annex No. 4 and Annex No. 8 to the Rules for Registration, as well as the documents executed during examination of the medical product registration dossier.

6. The list of documents submitted by the applicant in electronic form is determined by the Rules for Registration.

7. The documents in electronic form specified in paragraphs 4 and 5 of these Requirements are created in XML format in accordance with the standard “Extensible Markup Language (XML) 1.0 (Fifth

Edition)” (published in the Internet Information and Telecommunications Network at: <http://www.w3.org/TRyREC-xml>).

8. The structures of documents in electronic form specified in paragraphs 4 and 5 of these Requirements are a set of credentials that are arranged in a hierarchical form. Credentials of structures of documents in electronic form can include 1 or several nested credentials.

9. Description of the structure of documents in electronic form and rules for their completion are shown in tabular form with indication of the full composition of credentials, taking into account the hierarchy levels up to simple (atomic) credentials (Tables 1 to 7 and 10).

10. To indicate the compulsory completion of credentials, the following symbols are used in the column “Multiplicity” (“Mult.”) in Tables 1 to 7 and 10:

0 – credential is not filled;

1 – credential is mandatory;

0..1 – credential is optional, repetitions are not allowed;

0..* – credential is optional, can be repeated without restrictions;

1..* – credential is mandatory, can be repeated without restrictions;

n..m – credential is mandatory, should be repeated no less than n times and at most m times ($n > 1$, $m > n$).

11. In the column “Credential name” a credential name is indicated, and also a name of the corresponding details element in the technical scheme of the structure of the document in electronic form with the name space prefix is specified in parentheses.

II. Requirements to the structure of the document in electronic form “Details on application for registration of a medical product within the Eurasian Economic Union” (R.018)

12. To indicate rules for completion of credentials depending on the type of application, the following symbols are used:

“+” - credential can be completed for this type of application in accordance with its multiplicity;

“+ (n..m)” - credential can be filled for this type of application and should be repeated no less than n times and at most m times ($n \geq 0$, $m > n$).

If indication is not specified, the credential is not completed for this type of application.

13. Credential composition of the structure of the document in electronic form “Details on application for registration of a medical product within the Eurasian Economic Union” (R.018) and the general rules for their completion, depending on the type of application are given in Table 1.

14. Requirements to creation of XML documents in accordance with the structure of documents in electronic form “Details on application for registration of a medical product within the Eurasian Economic Union” (R.018) are given in Table 9.

Table 1

Composition of credentials of the structure of the document in electronic form
 “Details on application for registration of a medical product within the Eurasian Economic Union” (R.018)

Credential name	Rule for credential completion	Application for registration, application for examination	Application for change	Application for cancellation	Application for issuance of a duplicate	Mult.
1. Electronic document (details) code (csdo: EDocCode)	a code symbol of an electronic document (details) is indicated in accordance with the register of structures of electronic documents and data	+	+	+	+	1
2. Electronic document (details) identifier (csdo: EDocId)	a string of characters that uniquely identifies electronic document (details) is indicated	+	+	+	+	1
3. Identifier of the reference electronic document (details) (csdo: EDocRefId)	an identifier of the electronic document (data) in response to which this electronic document (details) was generated, is indicated					0..1
4. Date and time of the electronic document (details) (csdo: EDocDateTime)	date and time of the creation of the electronic document (details) is indicated	+	+	+	+	1
5. Details on the application for registration of a medical product and (or) related procedures (hccdo: MedicalDeviceApplicationDetails)	details on application for registration of a medical product and (or) registration related procedures are indicated	+	+	+	+	1
5.1. Number of the application for the medical product registration (hcsdo: MedicalProductApplicationId)	number of the application is indicated which is submitted by the authorized authority of the reference state in a form of a string of at most 20 characters in length, without string break characters, carriage return and tabulation according to template in accordance with paragraph 16 of the Procedure for the formation and maintenance of the information system in the field of circulation of medical products approved by Decision No. 30 of the Council of the Eurasian Economic Commission dated February 12, 2016					0..1
5.2. Document date (csdo: DocCreationDate)	date of application submission in accordance with GOST ISO 8601-2001 is	+	+	+	+	1

Credential name	Rule for credential completion	Application for registration, application for examination	Application for change	Application for cancellation	Application for issuance of a duplicate	Mult.
	indicated					
5.3. Reference state code (hcsdo:ReferenceUnifiedCountryCode)	a two-letter code of the reference state in which a medical product is supposed to be circulated, from the classifier of countries of the world in accordance with ISO 3166-1 is indicated	+	+	+	+	1
a) guide (classifier) identifier (attribute codeListId)	value "P.CLS.019" is indicated	+	+	+	+	1
5.4. Recognition state code (hcsdo:RecognitionUnifiedCountryCode)	a two-letter code of a recognition state in which a medical product is supposed to be circulated, from the classifier of countries of the world in accordance with ISO 3166-1 is indicated	+	+	+	+	0..*
a) guide (classifier) identifier (attribute codeListId)	value "P.CLS.019" is indicated	+	+	+	+	1
5.5 Code of the type of application for registration of a medical product and (or) related procedures (hcsdo: MedicalProduct ApplicationKindV2Code)	a code of the type of the submitted application in accordance with the classifier of document types of medical product registration dossier is indicated in a form of a string of at most 10 characters without string break characters, carriage return and tabulation	+	+	+	+	1
5.6. Description of the method to obtain information on the procedure for a medical product registration (hcsdo:InformationObtaining MethodText)	a description of the method to obtain information on the procedure for a medical product registration is indicated in a form of a string of at most 4,000 characters in length				+	0..1
5.7. Code of the method to obtain a registration certificate of the medical product (hcsdo: ReceptionKindCode)	a code of the method to obtain a registration certificate for the medical product is indicated in accordance with a list of possible values: 01 - on paper, personally; 02 - send it on paper by registered mail with notification of delivery; 03 - in a form of electronic document; 99 - other				+	0..1

Credential name	Rule for credential completion	Application for registration, application for examination	Application for change	Application for cancellation	Application for issuance of a duplicate	Mult.
5.8. Name of the method to obtain the registration certificate for a medical product (hcsdo:ReceptionKindName)	if credential “5.7. Code of the method to obtain the registration certificate for a medical product“ is filled with value “99” - “other”, a name of a method to obtain a registration certificate of the medical product is indicated in a form of a string of 500 characters or less, without string break characters, carriage return and tabulation				+	0..1
5.9. Reason for the Applicant's appeal (hcsdo: ReasonText)	description of the reason for cancellation (annulment) or the reason for applying for a duplicate of a registration certificate of a medical product is indicated in a form of a string of at most 4,000 characters in length			+	+	1
6. Details which prove payment of the duty for a medical product registration and (or) related procedures (hccdo: DutyProofDocDetails)	details of payment of the duty for the medical product registration and (or) registration-related procedures are indicated	+			+	0..*
6.1. Country code (csdo: UnifiedCountryCode)	a two-letter code of a Member State from the classifier of countries of the world is indicated in accordance with ISO 3166-1, to which duty for the medical product registration and (or) registration –related procedures was paid	+			+	1
a) guide (classifier) code (attribute codeListId)	value “P.CLS.019” is indicated	+			+	1
6.2. Code of the type of the duty for a medical product registration and (or) related procedures (hcsdo: DutyKindCode)	a code of the type of the duty for a medical product registration and (or) registration-related procedure is indicated in accordance with a list of possible values: 01 - duty for a medical product examination; 02 - duty for a medical product registration;	+			+	0..1

Credential name	Rule for credential completion	Application for registration, application for examination	Application for change	Application for cancellation	Application for issuance of a duplicate	Mult.
	03 - duty for examination of changes in the registration dossier; 04 - duty for issue of a duplicate of a registration certificate for a medical product					
6.3. Name of the type of the duty for a medical product registration and (or) related procedures (hcsdo: DutyKindName)	if credential “6.2. Code of the type of the duty for a medical product registration and (or) related procedures” is not filled, a name of the type of the duty for a medical product registration and (or) registration-related procedures is indicated in a form of a string of at most 500 characters in length without string break characters, carriage return and tabulation	+			+	0..1
6.4. Document name (csdoiDocName)	a name of the document, which confirms payment of the duty for the medical product registration and (or) registration-related procedures is indicated in a form of a string of at most 500 characters in length without string break characters, carriage return and tabulation	+			+	1
6.5. Document number (csdo:DocId)	a number of the document, which confirms payment of the duty for the medical product registration and (or) registration-related procedures, is indicated in a form of a string of at most 50 characters in length without string break characters, carriage return and tabulation	+			+	1
6.6. Document date (csdo:DocCreationDate)	a date of issue of the document, which confirms payment of the duty for the medical product registration and (or) registration-related procedures is	+			+	1

Credential name	Rule for credential completion	Application for registration, application for examination	Application for change	Application for cancellation	Application for issuance of a duplicate	Mult.
	indicated, in accordance with GOST ISO 8601-2001					
7. Details on the type of the change introduced to the medical product registration dossier (hccdo:RegistrationDossierAmendingKindDetails)	details on the type of the change introduced to the medical product registration dossier are indicated		+			0..*
7.1. Code of the change introduced to the medical product registration dossier (hcsdo:RegistrationDossierAmendingKindCode)	a code of the change introduced to the medical product registration dossier is indicated from the classifier of the types of changes introduced to the medical product registration dossier		+			0..1
7.2. Name of the type of the change introduced to the medical product registration dossier (hcsdo:RegistrationDossierAmendingKindName)	if credential “7.1. Code of the change introduced to the medical product registration dossier” is not filled, a name of the type of the change introduced to the medical product registration dossier is indicated in a form of a string of at most 4,000 characters in length		+			0..1
8. Details of the medical product registration in the manufacturing country or other country (hccdo:RegistrationDetails)	details of the medical product registration in the manufacturing country or other country are indicated	+	+	+	+	0..*
8.1. Country code (csdo:UnifiedCountryCode)	a two-letter code of the country in which the medical product was registered is indicated from the classifier of countries of the world in accordance with ISO 3166-1	+	+	+	+	1..*
a) guide (classifier) identifier (attribute codeListId)	value “P.CLS.019” is indicated	+	+	+	+	1
8.2. Registration certificate number (hcsdo:RegistrationCertificateId)	a unique number of the medical product registration certificate is indicated	+	+	+	+	1
8.3. Document date (csdo:DocCreationDate)	a date of issue of the medical product registration certificate is indicated in accordance with GOST ISO 8601-2001	+	+	+	+	1
8.4. Document validity period (csdo:	a validity period of the medical product	+	+	+	+	0..1

Credential name	Rule for credential completion	Application for registration, application for examination	Application for change	Application for cancellation	Application for issuance of a duplicate	Mult.
DocValidityDuration)	registration certificate is indicated in accordance with GOST ISO 8601-2001					
9. Details on the registered medical product (hccdo: Medical DeviceRegistration Details)	details on the registered medical product are indicated. For application for changes: 2 copies of the credential are completed in the application in electronic form: in the 1 st copy a credential value “An indicator of a new edition of the application details” should correspond to the value “Application details are not a new edition”, in the 2 nd copy a credential value “An indicator of a new edition of the application details” should correspond to the value “Application details are a new edition”	+ (1)	+ (1..2)	+ (1)	+ (1)	1..2
9.1. An indicator of a new edition of the application details (hcsdo: NewEditionIndicator)	an indicator that determines whether the application details are a new edition is indicated: 1 - application details are a new edition; 0 - application details are not a new edition			+		0..1
9.2. Registered medical product (hccdo: RegisteredMedical DeviceDetails)	details on the registered medical product are indicated	+	+	+	+	0..1
9.2.1. Medical product name (hcsdo: MedicalProductName)	a name of the medical product is indicated in a form of a string of at most 500 characters in length without string break characters, carriage return and tabulation	+	+	+	+	1
9.2.2. Description of the medical product purpose (hcsdo: DevicePurposeText)	details on the medical product purpose are indicated in a form of a string of at most 4,000 characters in length	+	+	+	+	0..1
9.2.3. Code of the medical product scope of application (hcsdo:MedicalProductUsageCode)	a code of the medical product scope of application is indicated from the classifier of the medical product scopes of application	+	+	+	+	0..1
9.2.4. Name of the medical product scope	if credential “9.2.3. Code of the medical	+	+	+	+	0..1

Credential name	Rule for credential completion	Application for registration, application for examination	Application for change	Application for cancellation	Application for issuance of a duplicate	Mult.
of application (hcsdo:MedicalProductUsageName)	product scope of application” is not completed, name of the medical product scope of application is indicated in a form of a string of at most 500 characters in length without string break characters, carriage return and tabulation					
9.2.5. Code of the class of the medical product potential risk (hcsdo:RiskClassCode)	a code of the class of the medical product potential risk is indicated in accordance with a list of possible values: 1 - low degree; 2a - medium degree; 2b - increased degree; 3 - high degree	+	+	+	+	0..1
9.2.6. Code of the medical product type (hcsdo: MedicalProduct ClassificationCode)	a value of a 6-digit digital code of the medical product type is indicated from the medical product nomenclature of the Eurasian Economic Union	+	+	+	+	0..1
9.2.7 Name of the medical product type (hcsdo:MedicalProduct ClassificationName)	a name of the medical product type is indicated from the medical product nomenclature of the Eurasian Economic Union if a code of the medical product type is not filled in a form of a string of at most 500 characters in length	+	+	+	+	0..1
9.2.8. Description of technical and (or) performance characteristics of the medical product (hcsdoiMedicalProductCharacteristicText)	details on technical and (or) performance characteristics of the medical product are indicated in a form of a string of at most 4,000 characters in length		+			0..1
9.2.9. Code of the requirement for a medical product sterilization (hcsdo: MedicalProductSterilizationCode)	a code of the requirement for a medical product sterilization is indicated in accordance with a list of possible values: 01 - non-sterile single-use medical products; 02 - sterile single-use medical products; 03 - sterilizable multiple-use medical products, sterility of which is provided	+	+			0..*

Credential name	Rule for credential completion	Application for registration, application for examination	Application for change	Application for cancellation	Application for issuance of a duplicate	Mult.
	both for the first application and for each subsequent application by appropriate sterilization methods; 04 - non-sterile multiple-use medical products; 05 - equipment for sterilization of medical products					
9.2.10. Medical product usage technology code (hcsdo: MedicalProductUsageTechnologyCode)	a medical product usage technology code is indicated in accordance with a list of possible values: 01 - inactive medical products, functioning of which does not require an energy source, except for energy generated by human body or gravitation force (gravity); 02 - active medical products, for functioning of which it is necessary to use an energy source other than that generated by human body or gravitation force (gravity); 03 - inactive implantable medical products; 04 - active implantable medical products; 05 - biomedical products, including materials such as products of cellular technologies and tissue engineering, bio-implants, self-degrading biopolymers, fabric adhesives and sutures; 06 - surgical instruments intended for surgical intervention (cutting, drilling, sawing, scraping, scraping, fastening, sliding, shearing, piercing); 07 - prosthetic and orthopedic products; 08 - technical means of rehabilitation of disabled people	+	+			0..*
9.2.11. Indicator of availability of a drug	an indicator of availability of a drug	+				0..1

Credential name	Rule for credential completion	Application for registration, application for examination	Application for change	Application for cancellation	Application for issuance of a duplicate	Mult.
product in the medical product (hcsdo: MedicalDrugAvailabilityIndicator)	product in the medical product: 1 - medicinal product contains a drug product; 0 - medicinal product does not contain a drug product					
9.2.12. Details on the medical product set (hccdo:MedicalProductSetDetails)	details of the medical product set are indicated	+	+	+	+	0..*
9.2.12.1. Code of the type of the component of the medical product set (hcsdo: MedicalProductSetKindCode)	a code of the type of the component of the medical product set is indicated in accordance with a list of types of components of medical products	+	+	+	+	1
9.2.12.2. Name of the model of the component of the medical product (hcsdo: ModelNumberName)	a name of a component of the medical product is indicated in a form of a string of at most 500 characters in length without string break characters, carriage return and tabulation	+	+	+	+	1
9.2.12.3. Details on the manufacturer of the medical product component (hccdo: MedicalProductSetManufacturerDetails)	details on the manufacturer of the medical product component are indicated	+	+			0..1
9.2.12.3.1. Business entity name (csdo: BusinessEntityName)	a name of the manufacturer of the medical product component is indicated in a form of a string of at most 500 characters in length without string break characters, carriage return and tabulation	+	+			1
9.2.12.3.2. Country code (csdo: UnifiedCountryCode)	a two-letter country code is indicated from the classifier of countries of the world in accordance with ISO 3166-1	+	+			1
a) guide (classifier) identifier (attribute codeListId)	value "P.CLS.019" is indicated	+	+			1
9.2.12.4. Number of medical product components (hcsdo:MedicalProductSetMeasure)	a number of medical product components is indicated in the form of a nonnegative integer in decimal numeration system	+	+	+	+	1
a) measurement unit (attribute measurement UnitCode)	a three-character code of measurement unit, corresponding to the value of "piece" from the classifier of measurement units	+	+	+	+	1

Credential name	Rule for credential completion	Application for registration, application for examination	Application for change	Application for cancellation	Application for issuance of a duplicate	Mult.
b) guide (classifier) identifier (attribute measurementUnitCodeListId)	identifier of the classifier of measurement units in the system of unified regulatory and reference information of the Union is indicated in a form of a string of at most 20 characters in length without string break characters, carriage return and tabulation	+	+	+	+	1
9.2.1.3. Description of indications for use (hcsdo: IndicationText)	a description of indications for use of the medical product is indicated in a form of a string of at most 4,000 characters in length		+			0..1
9.2.1.4. Description of contraindications of the medical product (hcsdo: ContraindicationText)	as description of contraindication of the medical product is indicated in a form of a string of at most 4,000 characters in length		+			0..1
9.2.1.5. Description of side effects from medical product use (hcsdo: ReactionText)	a description of side effects from medical product use is indicated in a form of a string of at most 4,000 characters in length		+			0..1
9.2.1.6. Medical product storage period (hcsdo: MedicalProductStorageDuration)	a medical product storage period is indicated in accordance with GOST ISO 8601-2001	+	+			0..1
9.2.1.7. Medical product warranty period (hcsdoiMedicalProductWarrantyDuration)	a medical product warranty period is indicated in accordance with GOST ISO 8601-2001	+	+			0..1
9.2.1.8. Description of medical product storage conditions (hcsdoiMedicalProductStorageConditionsText)	a description of medical product storage conditions is indicated in a form of a string of at most 4,000 characters in length	+	+			0..1
9.3. Details of the manufacture of the registered medical product (hccdo:MedicalDeviceManufacturingDetails)	details on the manufacture of the medical product are indicated	+	+	+	+	0..1
9.3.1. Code of the degree of organization participation in medical product manufacture (hcsdo:	a code of the degree of organization participation in medical product manufacture is indicated in accordance	+	+	+	+	0..1

Credential name	Rule for credential completion	Application for registration, application for examination	Application for change	Application for cancellation	Application for issuance of a duplicate	Mult.
ManufactureParticipationDegreeCode)	with a list of possible values: 01 - completely at this manufacturing site; 02 - partially at this manufacturing site; 03 - completely at another manufacturing site					
9.3.2. Details on the manufacture of the registered medical product (hccdoiMedicalDeviceManufacturerDetails)	details of on the manufacture of the medical product are indicated. Credential composition and rules for their completion are given in Table 2	+	+	+	+	1
9.3.3. Details on the manufacturing area of the registered medical product (hccdo:MedicalDeviceManufacturingAreaDetails)	details on the manufacturing area of the registered medical product are indicated. Credential composition and rules for their completion are given in Table 2	+	+	+	+	0..*
9.4. Details on the authorized representative of the medical product manufacturer (hccdo:MedicalDeviceRepresentativeDetails)	details on the authorized representative of the manufacture of the registered medical product are indicated. Credential composition and rules for their completion are given in Table 2	+	+	+	+	0..1
10. Applicant role indicator (hcsdoiApplicantRoleIndicator)	an indicator which determines, whether an applicant is a medical products manufacturer is indicated: 1 - the applicant is a medical product manufacturer; 0 - the applicant is an authorized representative of the medical product manufacturer	+	+	+	+	1

Table 2

Description of credentials “Details on the manufacturer of the registered medical product”, “Details on the manufacturing area of the registered medical product” and “Details on the authorized representative of the medical product manufacturer”

Credential name	Rule for credential completion	Mult.
1. Details on business entity (ccdo: BusinessEntityTypeCode)	Credential composition and rules for their completion are given in Table 3	0..1
2. Details on the authorization document (hccdo: ManufacturePermitDocDetails)	Credential composition and rules for their completion are given in Table 6	0..1
3. Details on the officer of the medical product manufacturing organization (hccdo: OfficerDetails)	Credential composition and rules for their completion are given in Table 7	1..*

Table 3

Description of credential composition “Details on business entity”

Credential name	Rule for credential completion	Mult.
1. Country code (csdo:UnifiedCountryCode)	a code of a country of a business entity is indicated from the classifier of countries of the world in accordance with ISO 3166-1	0..1
a) guide (classifier) code (attribute codeListId)	value “P.CLS.019” is indicated	1
2. Business entity name (csdo:BusinessEntityName)	a full name of a business entity is indicated in a form of a string of at most 300 characters in length without string break characters, carriage return and tabulation	0..1
3. Business entity short name (csdo: BusinessEntityBriefName)	a short name or corporate name of a business entity is indicated in a form of a string of at most 120 characters in length without string break characters, carriage return and tabulation	0..1
4. Code of legal organizational form (csdo:BusinessEntityTypeCode)	a code of legal organizational form is indicated from the classifier of legal organizational forms is indicated in a form of a string of at most 20 characters in length without string break characters, carriage return and tabulation	0..1
a) guide (classifier) identifier (attribute codeListId)	an identifier of the classifier of legal organizational forms in the system of unified regulatory and reference information of the Union is indicated in a form of a string of at most 20 characters in length	1
5. Name of the legal organizational form (csdo:BusinessEntityType Name)	if credential “4. Code of legal organizational form” is not completed, a name of a legal organizational form is indicated in a form of a string of at most 120 characters in length without string break characters, carriage return and tabulation without string break characters, carriage return and tabulation	0..1
6. Business entity identifier (csdo:BusinessEntityId)	a number (code) of the entry in the register (register book) of the business entity assigned at the state registration is indicated in a form of a string of at most 20 characters in length without string break	0..1

Credential name	Rule for credential completion	Mult.
	characters, carriage return and tabulation	
a) method of identification (attribute kindId)	before the inclusion of the guide of methods of identification of business entities into the resources of the system of unified regulatory and reference information of the Union, a code of the method of identification of business entities is indicated in accordance with a list of possible values: 1 - BIN (business identification number of the Republic of Kazakhstan); 2 - GRYUL (code of the state registration of legal entities of the Republic of Armenia); 3 - OGRN (primary state registration number in the Russian Federation); 4 - OGRNIP (primary state registration number of individual entrepreneur in the Russian Federation); 5 - OKOGU (code of the National Classifier of the Republic of Belarus “Public control and administration authorities”); 6 - OKPO (code of the National Classifier of Enterprises and Organizations of the Kyrgyz Republic); 7 - OKYULP (code of the National Classifier of the Republic of Belarus “Legal Entities and Individual Entrepreneurs”)	1
7. Unique customs identification number (csdo: UniqueCustomsNumberId)	a unique identification number of a business entity for the purpose of customs control is indicated in a form of a string of at most 17 characters in length without string break characters, carriage return and tabulation	0..1
8. Taxpayer identifier (csdo:TaxpayerId)	an identifier of a business entity in the register of taxpayers of the country of the taxpayer registration is indicated in a form of a string of at most 20 characters in length without string break characters, carriage return and tabulation	0..1
9. Registration reason code (csdo: TaxRegistrationReasonCode)	a 9-digit digital code identifying a reason of a tax registration of a business entity in the Russian Federation is indicated	0..1
10. Address (ccdo: SubjectAddressDetails)	Credential composition and rules for their completion are given in Table 4	0..*
11. Contact credential (ccdo: CommunicationDetails)	Credential composition and rules for their completion are given in Table 5	0..*

Table 4

Description of credential composition “Address”

Credential name	Rule for credential completion	Mult.
1. Code of the address type (csdo:AddressKindCode)	a code of the address type is indicated from the classifier of types of addresses in accordance with	0..1

Credential name	Rule for credential completion	Mult.
	a list of possible values: 01 - address of registration; 02 - actual address; 03 - postal address	
2. Country code (csdo:UnifiedCountryCode)	a two-letter country code from the classifier of countries of the world is indicated in accordance with ISO 3166-1	0..1
a) guide (classifier) identifier (attribute codeListId)	value "P.CLS.019" is indicated	1
3. Territory code (csdo:TerritoryCode)	a code of the administrative-territorial division is indicated in a form of a string of at most 17 characters in length without string break characters, carriage return and tabulation	0..1
4. Region (csdo: RegionName)	a region name is indicated in a form of a string of at most 120 characters in length without string break characters, carriage return and tabulation	0..1
5. District (csdo: DistrictName)	a district name is indicated in a form of a string of at most 120 characters in length without string break characters, carriage return and tabulation	0..1
6. City (csdo :CityName)	a city name is indicated in a form of a string of at most 120 characters in length without string break characters, carriage return and tabulation	0..1
7. Settlement (csdo: SettlementName)	if credential "6. City" is not filled, a settlement name is indicated in a form of a string of at most 120 characters in length without string break characters, carriage return and tabulation	0..1
8. Street (csdo: StreetName)	a street name is indicated in a form of a string of at most 120 characters in length without string break characters, carriage return and tabulation	0..1
9. Building number (csdo:BuildingNumberId)	a number of a house, unit, building is indicated in a form of a string of at most 50 characters in length without string break characters, carriage return and tabulation	0..1
10. Room number (csdo:	a number of office or flat is indicated in a form of a string of at most 20 characters in length	0..1

Credential name	Rule for credential completion	Mult.
RoomNumberId)	without string break characters, carriage return and tabulation	
11. Post code (csdo: PostCode)	a post code of the postal service enterprise is indicated in the form of a string consisting of capital letters of the Latin alphabet or numbers that can be separated by a hyphen, without string break characters, carriage return and tabulation	0..1
12. Post office box (csdo: PostOfficeBoxId)	a number of post office box of the postal service enterprise is indicated in a form of a string of at most 20 characters in length without string break characters, carriage return and tabulation	0..1

Table 5

Description of credential composition "Contact credential"

Credential name	Rule for credential completion	Mult.
1. Code of communication type (csdo:CommunicationChannelCode)	a code of one of communication types ("e-mail", "telefax", "telephone") is indicated in accordance with a list of possible values: AO - address of the site on Internet information and telecommunication network; EM - e-mail; FX - telefax; TE - telephone; TG- telegraph; TL - telex	0..1
2. Name of communication type (csdo: CommunicationChannelName)	if credential "1. Code of communication type" is not filled, a name of one of communication types ("e-mail", "telefax", "telephone") is indicated in a form of a string of at most 120 characters in length without string break characters, carriage return and	0..1

	tabulation	
3. Communication channel identifier (csdo: CommunicationChannelId)	a telephone number, fax number or e-mail address, depending on the type of communication is indicated in a form of a string of at most 1,000 characters in length without string break characters, carriage return and tabulation	1..*

Table 6

Description of credential composition “Information on the authorization document”

Credential name	Rule for credential completion	Mult.
1. Document name (csdo:DocName)	a name of the authorization document is indicated in a form of a string of at most 500 characters in length without string break characters, carriage return and tabulation	1
2. Document number (csdo:DocId)	a number of the authorization document is indicated in a form of a string of at most 50 characters in length without string break characters, carriage return and tabulation	1
3. Document creation date (csdo:DocCreationDate)	a date of issue of the authorization document is indicated in accordance with GOST ISO 8601-2001	1
4. Document validity period (csdo:DocValidityDuration)	a validity period of the authorization document is indicated in accordance with GOST ISO 8601-2001	1

Table 7

Description of credential composition “Details on the officer”

Credential name	Rule for credential completion	Mult.
1. Full name (ccdo:FullNameDetails)	first name, middle name and last name of the officer is indicated	1
1.1. First name (csdo: FirstName)	a first name of the officer is indicated in a form of a string of at most 120 characters in length without string break characters, carriage return and tabulation	0..1
1.2. Middle name (csdo: MiddleName)	a middle name of the officer is indicated in a form of a string of at most 120 characters in length without string break characters, carriage return and tabulation	0..1
1.3. Last name (csdo: LastName)	a last name of the officer is indicated in a form of a string of at most 120 characters in length without string break characters, carriage return and tabulation	0..1
2. Country code (csdo: UnifiedCountryCode)	a two-letter country code from the classifier of countries of the world is indicated in	1

	accordance with ISO 3166-1	
a) guide (classifier) identifier (attribute codeListId)	value "P.CLS.019" is indicated	1
3. Position code (hcsdo: PositionCode)	a position code from the classifier of employees positions is indicated in a form of a string of at most 10 characters in length without string break characters, carriage return and tabulation	0..1
4. Position name (csdo: PositionName)	if credential "3. Position code" is not completed, a position name is indicated in a form of a string of at most 120 characters in length without string break characters, carriage return and tabulation	0..1
5. Contact credential (ccdo: CommunicationDetails)	Credential composition and rules for their completion are given in Table 5	0..*

Table 8

Requirements to the creation of XML documents in accordance with the structure of the document in electronic form “Details on application for registration of a medical product within the Eurasian Economic Union” (R.018)

Item No.	Element designation	Description
1	2	3
1	Code used to generate XML-document of the structure of electronic documents (details) in the registry of electronic document and details structures	R.018
2	The used version of electronic document (details) structure	1.0.0
3	Root element of XML-document	MedicalProductApplicationDetails
4	Identifier of name space of XML-document	um:EEC:R:MedicalProductApplicationDetails:v1.0.0
5	XML-scheme file name	EEC_R_MedicalProductApplicationDetails v1.O.O.xsd
6	Imported name spaces	a list of imported name spaces is given in Table 9. Symbols “X.X.X.” in imported name spaces correspond to number of versions of the basic data model and data model of subject area, used when developing schemes of structures of the electronic document (details) in accordance with paragraph 2 of Decision No. 78 of the Board of the Eurasian Economic Commission dated June 30, 2017

Table 9

Imported name spaces		
Item	Name space identifier	Prefix

No.		
1	2	3
1	um:EEC:M:ComplexDataObjects:vX.X.X	ccdo
2	um:EEC:M:HC:ComplexDataObjects:vX.X.X	hccdo
3	urn: EEC: M: HC: SimpleDataObjects: vX.X.X	hcsdo
4	um:EEC:M:SimpleDataObjects:vX.X.X	csdo

III. Requirements to the structure of the document in electronic form
“Details on documents of the medical product registration dossier or documents executed during examination of the medical product registration dossier” (R.020)

15. Credential composition and general requirements for completion of credentials of the structure of the document in electronic form. “Details on documents of the medical product registration dossier or documents executed during examination of the medical product registration dossier” (R.020) is given in Table 10.

16. When submitting the documents of the registration dossier in electronic form, for which the requirements for the structure are not specified, the file included in the structure of the file in *.pdf format should contain a text layer.

17. Requirements to creation of XML-document in accordance with the structure of the document in electronic form “Details on documents of the medical product registration dossier or documents executed during examination of the medical product registration dossier” (R.020) is given in Table 11.

Table 10

Description of credential composition of the structure of the document in electronic form
“Details on documents of the medical product registration dossier or documents executed during examination of the medical product registration dossier” (R.020)

Credential name	Rule for credential completion	Mult.
1. Electronic document (details) code (csdo: EDocCode)	a code symbol of an electronic document (details) is indicated in accordance with the register of structures of electronic documents and details	1
2. Electronic document (details) identifier (csdo: EDocId)	a string of characters that uniquely identifies electronic document (details) is indicated	1
3. Identifier of the reference electronic document (details) (csdo: EDocRefId)	an identifier of the electronic document (data) in response to which this electronic document (details) was generated, is indicated	0..1
4. Date and time of electronic document (details) (csdo: EDocDateT ime)	a date and time of electronic document (details) creation is indicated	1
5. Country code (csdo: UnifiedCountryCode)	a two-letter country code, which sent the document, is indicated from the classifier of countries of the world in accordance with	1

	ISO 3166-1	
a) guide (classifier) identifier (attribute codeListId)	value "P.CLS.019" is indicated	1
6. Number of application for medical product registration (hcsdo: MedicalProductApplicationId)	a number of application for registration assigned by the authorized authority of the reference state or other procedures related to the registration of the medical product is indicated in a form of a string of at most 20 characters in length without string break characters, carriage return and tabulation by a template in accordance with paragraph 16 of the Procedure for the formation and maintenance of information system in the field of circulation of medical products approved by Decision No. 30 of the Council of the Eurasian Economic Commission dated February 12, 2016	0..1
7. Registration certificate number (hcsdo: RegistrationCertificateId)	a registration certificate number is indicated in a form of a string of at most 50 characters in length without string break characters, carriage return and tabulation	0..1
8. Details on the document executed during examination of the medical product registration dossier or the document contained in the medical product registration dossier (hccdo: MedicalProductRegistrationDossierDetails)	details on the documents executed during examination of the medical product registration dossier or the document contained in medical product registration dossier are indicated. The credential consists of values of the attached credential specified in paragraphs 8.1 to 8.11 of this table	1..*
8.1. Indicator that the document belongs to the registration dossier (hcsdo:MedicalRegistrationFileIndicator)	an indicator that determines that the document belongs to the registration dossier is indicated: 1 - document of the registration dossier; 0 - documents executed during examination of the registration dossier	0..1
8.2. Document number (csdo:DocId)	a number of the document of the registration dossier or document executed during examination of the registration dossier is indicated in a form of a string of at most 50 characters in length without string break characters, carriage return and tabulation	0..1
8.3. Document name (csdo: DocName)	a name of the document of the registration dossier or document executed during examination of the registration dossier is indicated in a form of a string of at most 500 characters in length without string break characters, carriage return and tabulation	0..1
8.4. Code of the type of the document	a code of the type of the document of the medical	0..1

contained in the medical product registration dossier (hcsdo: MedicalProductRegistrationDocCode)	product registration dossier from the classifier of types of documents of the medical product registration dossier is indicated in a form of a string of at most 10 characters in length without string break characters, carriage return and tabulation	
8.5. Name of the type of the document contained in the medical product registration dossier (hcsdo: MedicalProductRegistrationDocName)	if credential “8.4. Code of the type of documents contained in the medical product registration dossier” is not completed, a name of the type of the document contained in the medical product registration dossier is indicated in a form of a string of at most 500 characters in length without string break characters, carriage return and tabulation	0..1
8.6. Code of the type of the documents executed during examination of the medical product registration dossier (hcsdo: MedicalProductRegistrationFileCode)	a code of the type of the document, executed during examination of the medical product registration dossier is indicated from the classifier of types of documents executed during examination of the medical product registration dossier, in a form of a string of at most 10 characters in length without string break characters, carriage return and tabulation	0..1
8.7. Name of the type of the document, executed during examination of the medical product registration dossier (hcsdo: MedicalProductRegistrationFileName)	if credential “8.6. Code of the type of the document, executed during examination of the medical product registration dossier” is not completed, a name of the type of the document, executed during examination of the medical product registration dossier is indicated in a form of a string of at most 500 characters in length without string break characters, carriage return and tabulation	0..1
8.8. Document creation date (csdo: DocCreationDate)	a date of issue of the registration dossier document or document executed during examination of the registration dossier is indicated in accordance with GOST ISO 8601-2001	1
8.9. Document expiration date (csdo: DocValidityDate)	an expiration date of the registration dossier document or document executed during examination of the medical product registration dossier is indicated in accordance with GOST ISO 8601-2001	0..1
8.10. Name of a business entity (csdo: BusinessEntityName)	a name of organization issued a registration dossier document or document executed during examination of the registration dossier is indicated in a form of a string of at most 300 characters in length without string break characters, carriage return and tabulation	0..1
8.11. Description of the element of the registration dossier document or document executed during examination of the registration dossier (hcsdo: MedicalAttributeEnumText)	a description of the additional indicator of the registration dossier document or document executed during examination of the registration dossier is indicated in a form of a string of at most 4,000 characters in length	0..*

a) code of the type of the element of the registration dossier document or document executed during examination of the registration dossier (attribute MedicalAttribute KindEnumCode)	a code symbol of the type of an additional indicator of the registration dossier document or document executed during examination of the registration dossier, in accordance with a list of possible values: 01 - time of response for request; 02 - supporting document number; 03 - type of the registration dossier document in respect of which the request is sent; 04 - type of the document executed during examination of the registration dossier in respect of which the request is sent; 05 - path to the file in the dossier structure; 06 - name of the file to be replaced; 99 - other	0..1
b) name of the type of the document element (attribute AttributeKind Name)	if credential “a) code of the type of document element” is not completed, a name of the type of an additional indicator of the registration dossier document or document executed during examination of the registration dossier is indicated in a form of a string of at most 500 characters in length without string break characters, carriage return and tabulation	0..1
8.12. Document in binary format (hcsdo:DocCopyBinaryText)	a registration dossier document or document executed during examination of the registration dossier, in the form of file in *.pdf (scanned copy) format, for which the requirements for electronic form are defined in the form of a sequence of binary octets (bytes). It is completed in a mandatory manner if credential “8.11. document in XML format” is not completed	0..1
a) Data format code (attribute mediaTypeCode)	a code symbol of data format type “*.pdf” is indicated	1
8.13. Document in XML format (ccdo:AnyDetails)	a registration dossier document or document executed during examination of the registration dossier in XML format for which the requirements for electronic form are defined is indicated in the form of a sequence of binary octets (bytes). It is completed in a mandatory manner if credential “8.13. PDF document” is not completed	0..1
8.13.1. XML-document	a XML-document of a free structure is indicated	1..*
9. Note (csdo:NoteText)	an additional explanatory text is indicated in a form of a string of at most 4,000 characters in length	0..1

Table 11

Requirements to creation of XML-document in accordance with the structure of the document in electronic form “Details on documents of the medical product registration dossier or documents executed during examination of the medical product registration dossier” R.020)

Item No.	Element designation	Description
1	2	3
1	Code of the structure of electronic documents (details) used to generate XML-document in the registry of electronic document and details structures	R.020
2	The version used of electronic documents (details) structure	1.0.0
3	Root element of XML-document	MedicalProductRegistrationDocumentDetails
4	Identifier of name spaces of XML-document	urn: EEC :R: MedicalProductRegistrationDocumentDetailsiv 1.0.0
5	Name of the file XML-scheme	EEC_R_MedicalProductRegistrationDocumentDetails_v1.0.0.xsd
6	Imported name spaces	a list of imported name spaces is given in Table 12. Symbols “X.X.X.” in imported name spaces correspond to number of versions of the basic data model and data model of subject area, used when developing schemes of structures of the electronic document (details) in accordance with paragraph 2 of Decision No. 78 of the Board of the Eurasian Economic Commission dated June 30, 2017.

Table 12

Imported name spaces

Item No.	Name space identifier	Prefix
1	2	3
1	um:EEC:M:ComplexDataObjects:vX.X.X	ccdo
2	um:EEC:M:HC:ComplexDataObjects:vX.X.X	hccdo
3	urn: EEC: M: HC: SimpleDataObjects: vX.X.X	hcsdo
4	um:EEC:M:SimpleDataObjects:vX.X.X	csdo

Seal:

Eurasian Economic Commission. For documents